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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/698,705	10/27/00	DEVAUX B	P1777R1

HM22/1023

ATTN: LEE K. TAN
GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO CA 94080-4990

EXAMINER	
DAVIS,N	
ART UNIT	**PAPER NUMBER**
1642	8

DATE MAILED: 10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/698,705	Applicant(s) DEVAUX ET AL.	
	Examiner Natalie A. Davis	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-21 and 29-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-21 and 29-33* is/are rejected.

7)☒ Claim(s) *19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, 29-33, and 56 (claim 29, as it reads on claim 2), drawn to an anti-prostate stem cell antigen antibody, classified in class 530, subclass 387.7.

II. Claims 15-21 and 29-33 (claim 29, as it reads on claim 15), drawn to an anti-PSCA monoclonal antibody that inhibits the growth of PSCA expressing cells, classified in class 530, subclass 388.1.

III. Claims 22-27, drawn to an isolated nucleic acid, vector, and host cell, classified in class 536, subclass 23.1.

IV. Claim 28, drawn to a method of producing the antibody of claim 2, classified in class 435, subclass 70.1.

V. Claims 34-45, drawn to a method of killing a PSCA-expressing cancer cell, classified in class 424, subclass 130.1.

VI. Claims 46-55 and 57, drawn to a method of alleviating PSCA-expressing cancer in a mammal, classified in class 424, subclass 141.1.

A. In the event applicant elects Group I, claims 1-14, 29-33, and 56, applicant is required to elect a single species of antibody sequence, comprising:

Species A, drawn to SEQ ID NO: 10

Species B, drawn to SEQ ID NO: 11

Species C, drawn to SEQ ID NO: 12

Species D, drawn to SEQ ID NO: 13

Species A-D are patentably distinct based on structural and functional differences and mode of action, as species may target different receptors.

B. In the event applicant elects Group III, claims 1-14, 29-33, and 56, applicant is required to elect a single species of nucleic acid, comprising:

Species E, drawn to SEQ ID NO: 3

Species F, drawn to SEQ ID NO: 4

Species G, drawn to SEQ ID NO: 5

Species H, drawn to SEQ ID NO: 6

Species I, drawn to SEQ ID NO: 7

Species J, drawn to SEQ ID NO: 8

Species K, drawn to SEQ ID NO: 9

Species L, drawn to SEQ ID NO: 10

Species M, drawn to SEQ ID NO: 11

Species N, drawn to SEQ ID NO: 12

Species O, drawn to SEQ ID NO: 13

Species E-O are patentably distinct based on structural and functional differences and mode of action, as species may target different receptors.

The inventions are distinct, each from the other because of the following reasons:

2. The Inventions of Groups I-III (products) and IV-VI (methods) are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Groups I-III may be used for a number of different processes that are very much unrelated. For example, the antibodies of Groups I-II may not only be used in the method of Group V, but may also be used for immunopurification. Likewise, the nucleic of Group IIII may be used as a probe and not only used in a cell to make an antibody.

3. The products of Groups I-III are drawn to structurally and functionally different molecules with different immunological properties, each invention requires different reagents and steps to make and characterize it. For example, an antibody is structurally and functionally very different from a nucleic acid. The antibodies of Groups I and differ in that the antibody of Group I may be chimeric and competes for the same epitope as another monoclonal antibody and does not inhibit growth of tumors cells unless conjugated to a growth inhibitory agent, whereas the antibody of Group II is a monoclonal antibody that alone is capable of inhibiting tumor cell growth, is produced in bacteria and may be in human form.

4. The methods of Groups IV-VI relate to methods but each method differs in method steps, modes of operation, reagents needed and serve different endpoints and effects.

5. During a telephone conversation with Attorney Tran on 30 August 2001 a provisional election was made with traverse to prosecute the invention of Group II, claims 15-21 and 29-33. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-14, 22-28, and 34-57 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 15-21, and 29-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Reiter, et al., (1998, '03).

9. The elected claims are drawn to an anti-PSCA monoclonal antibody that inhibits the growth of PSCA-expressing cancer cells in vivo. The claims are further drawn to an antibody that internalizes upon binding to PSCA on the cell, is humanized or human, produced in a bacteria, comprised in a composition with a carrier, and may be conjugated to a cytotoxic agent.

10. Reiter, et al., disclose monoclonal antibodies that specifically bind to PSCA (p. 10), which destroy prostrate cancer cells (page 3). Reiter, et al. further disclose antibodies conjugated to a cytotoxic agent (p. 13-14), pharmaceutical compositions comprising antibodies (page 27),

and antibodies produced in bacteria. It is inherent that the cytotoxic agent is a maytansinoid, the antibody is human, since it is derived from and used to treat human prostate cancer, and that the antibody is internalized upon binding to PCSA because PCSA is found both internally and externally. Thus, the prior art reference anticipates the invention as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, Ph.D.
October 19, 2001

GEETHA P. BANSAL
PRIMARY EXAMINER